UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,963	07/26/2000	Hans Josef Stauss	ICI 101	8595

23579 7590 06/02/2006

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/625,963	STAUSS ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,15 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,15 and 19* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02072006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of Application Serial Number PCT/GB99/03572.

Claims 2-4, 6, 8-14, 16-18, 20-48 have been canceled.

Claims 1, 5, 7, 15 and 19 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment and the Rule 131 declaration of inventors Stauss and Gao filed March 14, 2006 only the following ground of rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 5, 15 and 19 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was previously stated: "The claims are broadly drawn to any peptide of 9-100 amino acid residues in length comprising the core amino acid sequence RMFPNAPYL (SEQ ID NO: 1), wherein the peptide is processed by HLA-A0201 APCs to produce the peptide of SEQ ID NO: 1. However, the specification teaches only one peptide comprising the RMFPNAPYL amino acid sequence and that is the 9-mer of SEQ ID NO: 1. The specification does not teach any peptides of 10-100 amino acid residues in length that can be processed by APCs to yield the RMFPNAPYL peptide. Applicant has not disclosed whether the HLA-A0201 APCs are professional APCs or non-professional APCs. HLA-A0201 is an MHC class I antigen and is therefore expressed upon all cells in the body, not just on professional APCs. Antigen processing is different between professional APCs and other cells in the body. Professional APCs process antigen in a specialized proteasome called an immunoproteasome. Other types of cells in the body produce antigenic fragments in a standard proteasome. It is known in the art that the antigenic fragments produced by the two types of proteasome are different, due to differences in enzymatic cleavage sites (see e.g., Morel et al. (Immunity [2000] 12:107-117; U on form PTO-892, newly cited). Furthermore, the presence of HLA-A0201 on the surface of the APC does not affect the peptides produced by the APC, only which peptides are presented on the surface of the cell in the context of MHC class I to a corresponding T cell. In other works, a non-HLA-A0201 APC may also produce the antigenic peptide of SEQ ID NO: 1, but that peptide will not be presented upon the surface of the APC to a T cell. Accordingly, Applicant has not demonstrated the possession of the full genus of 9-100 amino acid residue peptides that can be processed by an HLA-A0201 APC to yield the RMFPNAPYL peptide. Within the genus, Applicant has only demonstrated the possession of the 9-mer peptide of SEQ ID NO: 1. Adequate

written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016).

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115)."

Applicant's arguments filed March 15, 2006 have been fully considered but they are not persuasive.

Applicant asserts that the claims meet the legal standard for written description because, "[a]lthough the 'written description' requirement is a separate requirement from the 'enablement' requirement, if the enablement requirement has been met, it is difficult for the Examiner to assert that the written description requirement has not been met," further noting that the Examiner had withdrawn the previous rejection of the claims for lack of enablement. Applicant asserts that the claims meet the legal standard for written description because the sequence of human WT-1 polypeptide is known in the art, the claimed peptide contains RMFPNAPYL with N- and C- terminal extensions derived from the sequence of WT-1 and the sequence can be processed by HLA-A0201+ APCs to yield the RMFPNAPYL peptide. Applicant's interpretation of the relationship between enablement and description is incorrect. The Court has stated that it is possible for a specification to enable the practice of an invention as broadly as it is claimed and still not describe that invention. The Court gave as an example the situation where the specification discusses only compound A and contains no broadening language of any kind. This discussion might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described. See *In re* DiLeone & Lucas, 168 USPQ 592 (CCPA 1971). In the instant case, Applicant has described the peptide of SEQ ID NO: 1 as being a fragment of the gagta-1 polypeptide encoded by the Wilms' tumor antigen gene (page 3, lines 5-9 and page 8, lines 1-13 for example). The specification further discloses preferred sizes for the polypeptide and that the peptide bind to HLA-0201 (page 7 for example). However, other than the gata-1 polypeptide, the specification does not teach:

1) the sequence of any other peptide comprising 9-100 amino acids and having the amino acid sequence of SEQ ID NO: 1 contained therein

2) the identity of residues which constitute the cleavage sites for the processing by HLA-A0201 APCs to produce the peptide of SEQ ID NO: 1 as recited in the claims, or

3) the identity of any enzyme that would facilitate the cleavage of the claimed 9-100 amino acid peptide into the HLA-0201 identifiable sequence of SEQ ID NO: 1.

Accordingly, while the artisan may well be able to make and use a genus of peptide as broadly recited in the claims, the single species disclosed in the specification does not provide an adequate written description of the entire genus to show that it was indeed in Applicant's possession at the time the invention was made.

Conclusion

2. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. FV
Patent Examiner
May 26, 2006

David a Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644